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**Published:**
— *With international search report.*

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

WO 01/27210 A1

(54) Title: MEDICAMENT DELIVERY DEVICE WITH MOISTURE RESISTANT COATING

(57) Abstract: There is described a reservoir means which means is provided with a moisture resistant coating, the reservoir means is especially adapted to contain a medicament. There is also described a medicament delivery device which comprises a medicament reservoir, a medicament delivery passage and a metering member characterised in that the device includes a surface or surfaces provided with a moisture resistant coating. The device is especially an inhaler, e.g. a dry powder inhaler. A method of treating a respiratory disorder is also described which comprises administering of a therapeutically effective amount of a pharmaceutically active agent to a patient suffering from such a disorder.

# MEDICAMENT DELIVERY DEVICE WITH MOISTURE RESISTANT COATING

This invention relates to a novel form of reservoir means, such as a medicament capsule and the like and to a delivery device e.g. an inhaler, for use in administering a medicament in such a reservoir means.

Many medicament delivery devices, such as inhalers, make use of medicament in a finely divided powder form. The powder may be located within the delivery device, for instance, in a single storage compartment or in a plurality of single dose locations.

One form of inhaler may make use of medicament powder which is located within a frangible, plastic capsule. In use, the capsule is inserted into the inhaler and operation of the inhaler ruptures from the plastic capsule so that the powder may be extracted from the capsule and inhaled by the user.

A problem encountered with many such devices making use of powdered medicament is that, if moisture comes into contact with the powder, it will tend to make it less free-flowing and therefore render the operation of the device less effective because the correct dose of powder cannot be fully delivered.

Moisture may access the powder via several different mechanisms. These include the passage of the moisture through, for example, the plastic wall of encapsulated powder for those inhalers which make use of capsules loaded with medicament powder. For those inhalers which include a storage compartment loaded with powder and from which a dose of powder is accessed by some form of moving part within the inhaler and then presented to an air passageway for inhalation, moisture can access powder within the storage compartment by finding its way along a gap or gaps between the moving parts. In some inhalers there is the possibility of a "wick" type path being established between the powder in a storage compartment within the inhaler and a location within the inhaler where a dose of medicament is located.

With inhalers where a plurality of single doses of medicament is located within the inhaler, there is again likely to be one or more moving parts, providing gaps along which moisture may travel to access each individual dose of medicament.

It is also possible that moisture can pass through the plastic walls of inhalers and reach the powder contained within the inhaler whether in a single storage compartment or in individual dosage locations.

International Patent Application No WO 00/12163 describes the use of a Parylene coating on the inner surface of the metering chamber which is intended to mitigate the deposition of medicament particles on the inner walls of a metered dose inhaler (MDI) for the delivery of medicament via a pressurised aerosol.

We have now surprisingly found that a moisture resistant coating, e.g. a Parylene coating, may be used as on a medicament reservoir and/or a medicament delivery device, such as an inhaler, to render the device, and especially the medicament chamber, moisture resistant.

According to a first aspect of the invention we provide a reservoir means which means is provided with a moisture resistant coating.

In a preferred embodiment, the reservoir means contains medicament such that the reservoir means may be used in conjunction with a delivery device.

The reservoir means may be any conventionally known reservoir means, such as a bulk medicament reservoir or one or more single dose reservoir means. The reservoir means shall not include a pressurised canister for use in inhalation therapy as described in the prior art. When the reservoir means is a single dose reservoir, such as a capsule, e.g. a conventional gelatin capsule, or a spool and spool carrier as described in International Patent Application No. WO93/16748, the coating may be on the inner walls or the outer walls of the reservoir means. However, preferably, the

reservoir means is coated on the outer walls, such that the reservoir means is substantially sealed in the coating and is rendered moisture proof.

According to a further feature of the present invention we provide a medicament delivery device which comprises a medicament reservoir as hereinbefore described.

In an especially preferred embodiment the medicament delivery device is also provided with a moisture resistant coating. Such a coating preferentially covers substantially the whole of the delivery device.

When the medicament reservoir means comprises a bulk reservoir, then the medicament delivery device may preferentially include a metering member. The metering member preferably is also provided with a moisture resistant coating.

According to a yet further feature of the invention we therefore provide a medicament delivery device which comprises a medicament reservoir, a medicament delivery passage and a metering member characterised in that the device is provided with a moisture resistant coating on one or more surfaces. Preferably, the whole of the device is substantially provided with a moisture resistant coating.

The moisture resistant coating may be provided on one or more external or internal surfaces of the body of the medicament delivery device. The moisture resistant coating preferentially coats one or more surfaces of the bulk medicament reservoir. Other surfaces of the body of the medicament delivery device may also be provided with a moisture resistant coating.

The moisture resistant coating may be in the form of any material which is effective to prevent moisture accessing the powder. Typically, it may be applied to those surfaces between which there may be a gap due to relative movement between the surfaces when the inhaler is in use. However, the moisture resistant coating may be applied additionally or alternatively to other surfaces including the whole or part of

the external surface of the inhaler in order to prevent moisture passing into the interior of the inhaler through the walls thereof.

The moisture resistant coating should, of course, be sufficiently stable and robust so that damage to the coating during use of the delivery device.

The moisture resistant coating of the invention may be applied to any conventionally known medicament delivery system. However, in a preferred embodiment, the medicament delivery device is an inhaler. Whilst the moisture proof barrier may be applied to any conventionally known inhaler, it is an especially preferred aspect of the invention for the inhaler to be a dry powder inhaler (DPI).

Thus, in a preferred embodiment we provide an inhaler, e.g. a DPI, in which the medicament reservoir is provided with a moisture resistant coating.

Dry powder inhalers are known, such as TECHNOHALER, being developed by Innovata Biomed in the UK. WO 93/16748 describes an inhaler which comprises a disc-like cartridge having a plurality of medicament carrying capsules around its periphery. Each capsule comprises a spool carrier which houses a spool. Each spool has a flange at each end which form a tight slidable fit within the body of the spool carrier. The space left between the body of the spool and the spool carrier is filled with an appropriate medicament.

In a preferred embodiment we provide a dry powder inhaler wherein the medicament reservoir comprises one or more individual medicament capsules, e.g. spool carriers and wherein each medicament capsule is provided with a moisture resistant coating. Preferably, the medicament capsule is sealed in a moisture resistant coating.

A variety of medicaments may be administered by using the inhaler of the invention. Such medicaments are generally (but not limiting), bronchodilators or other anti-asthma drugs or antibiotics. Such medicaments include, but are not limited to $ß_2$-

agonists, e.g. fenoterol, formoterol, pirbuterol, reproterol, rimiterol, salbutamol, salmeterol and terbutaline; non-selective beta-stimulants such as isoprenaline; xanthine bronchodilators, e.g. theophylline, aminophylline and choline theophyllinate; anticholinergics, e.g. ipratropium bromide; mast cell stabilisers, e.g. sodium cromoglycate and ketotifen; bronchial anti-inflammatory agents, e.g. nedocromil sodium; and steroids, e.g. beclomethasone dipropionate, fluticasone, budesonide and flunisolide; and combinations thereof.

Specific combinations of medicaments which may be mentioned include combinations of steroids, such as, beclomethasone dipropionate, fluticasone, budesonide and flunisolide; and combinations of to $ß_2$-agonists, such as, formoterol and salmeterol. It is also within the scope of this invention to include combinations of one or more of the aforementioned steroids with one or more of the aforementioned $ß_2$-agonists.

Further medicaments may include proteinaceous compounds and/or macromolecules, for example, leuprolide and alpha interferon; hormones, such as insulin, human growth hormone, parathyroid hormone; growth factors, anticoagulants, immunomodulators, cytokines and nucleic acids.

According to a yet further feature of the invention we provide a method of treating a respiratory disorder which comprises the administering of a therapeutically effective amount of a pharmaceutically active agent to a patient suffering from such a disorder.

The moisture resistant coating is preferentially a biocompatible coating. Such coatings include, but are not limited to, sugars.

Polymers of poly-para-xylylenes are known as parylene. This material is a conformal polymer film which has been used in a number of applications, including electronics circuits and sensor, where environmental and dielectric isolation is required.

We further the use of a parylene in the manufacture of a moisture resistant capsule as hereinbefore described.

Parylenes are thermoplastic polymers that are capable of polymerising on surfaces from an active monomer gas, without the presence of a liquid. The process is capable of producing very thin layers of polymer and, indeed, a layer of from 10 to 20 microns may be sufficient to protect inhalers and their parts from ingress of moisture.

The polymerisation process takes place at room temperature without solvents and additives. Since the parylene is applied as a gas it conforms to the topography of the surface which it contacts. Since the process does not involve a liquid phase, there is no pooling and bridging during application. The coating is free of pinholes even if the coating has a thickness of less than one micron. As well as being resistant against moisture, parylene is also resistant against other media including hydrocarbons, acids and blood.

The coating may be applied in a single vacuum-coating operation in a thickness from 0.025 to 75 microns and can be controlled accurately to ± 10% of the final thickness.

## CLAIMS

1. A reservoir means which means is provided with a moisture resistant coating.

2. A reservoir means according to claim 1 characterised in that the reservoir means contains a medicament.

3. A reservoir means according to claim 1 characterised in that the reservoir means is a bulk medicament reservoir.

4. A reservoir means according to claim 1 characterised in that the reservoir means comprises one or more single dose reservoir means.

5. A reservoir means according to claim 1 characterised in that the reservoir means is coated on the outer walls, such that the reservoir means is substantially sealed in the coating and is rendered moisture proof.

6. A reservoir means according to claim 1 characterised in that the reservoir means comprises a spool carrier housing a spool.

7. A reservoir means according to claim 1 characterised in that the moisture resistant coating is a biocompatible coating.

8. A reservoir means according to claim 7 characterised in that the biocompatible coating is a sugar.

9. A reservoir means according to claim 7 characterised in that the moisture resistant coating is a polymer.

10. A reservoir means according to claim 9 characterised in that the polymer is a poly-para-xylylene (parylene).

11. A reservoir means according to claim 1 characterised in that the moisture resistant coating has a thickness of from 0.025 to 75 microns.

12. A medicament delivery device which comprises a medicament reservoir according to claim 1.

13. A medicament delivery device according to claim 7 characterised in that the delivery device is also provided with a moisture resistant coating.

14. A medicament delivery device according to claim 8 characterised in that the moisture resistant coating covers substantially the whole of the delivery device.

15. A medicament delivery device according to claim 6 characterised in that the medicament reservoir means comprises a bulk reservoir.

16. A medicament delivery device according to claim 9 characterised in that the medicament delivery device includes a metering member.

17. A medicament delivery device according to claim 10 characterised in that the metering member is also provided with a moisture resistant coating.

18. A medicament delivery device according to claim 6 characterised in that the medicament reservoir comprises a single dosage reservoir.

19. A medicament delivery device according to claim 12 characterised in that the moisture resistant coating is applied to the outer surface of the reservoir.

20. A medicament delivery device according to claim 18 characterised in that the medicament reservoir comprises a plurality of single dose units hosed in a cartridge.

21. A medicament delivery device according to claim 14 characterised in that the cartridge is also provided with a moisture resistant coating.

22. A medicament delivery device according to claim 6 characterised in that the medicament delivery device is an inhaler.

23. A medicament delivery device according to claim 23 characterised in that the inhaler is a dry powder inhaler (DPI).

24. A medicament delivery device according to claim 23 characterised in that the dry powder inhaler is a TECHNOHALER.

25. A medicament delivery device according to claim 6 characterised in that the moisture resistant coating is a biocompatible coating.

26. A medicament delivery device according to claim 25 characterised in that the biocompatible coating is a sugar.

27. A medicament delivery device according to claim 6 characterised in that the moisture resistant coating is a polymer.

28. A medicament delivery device according to claim 27 characterised in that the polymer is a poly-para-xylylene (parylene).

29. A medicament delivery device according to claim 6 characterised in that the moisture resistant coating has a thickness of from 0.025 to 75 microns.

30. A method of treating a respiratory disorder which comprises the administering of a therapeutically effective amount of a medicament to a patient suffering from such a disorder wherein said medicament is contained in a reservoir.

31. The use of a parylene in the manufacture of a moisture resistant reservoir according to claim 10 and/or a medicament delivery device according to claim 28.

32. A reservoir means or a medicament delivery device substantially as described with reference to the accompanying description.

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

HARRISON GODDARD FOOTE
Tower House
Merrion Way
Leeds LS2 8PA
GRANDE BRETAGNE

08.JAN.2002* 3412

# PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

| | |
|---|---|
| Date of mailing *(day/month/year)* | 03.01.2002 |
| Applicant's or agent's file reference: SPG/P36234WO | **IMPORTANT NOTIFICATION** |

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/GB00/03892 | 11/10/2000 | 11/10/1999 |

Applicant
INNOVOTA BIOMED LIMITED

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

| Name and mailing address of the IPEA/ | Authorized officer |
|---|---|
| European Patent Office<br>D-80298 Munich<br>Tel: +49 89 2399 - 0 Tx: 523656 epmu d<br>Fax: +49 89 2399 - 4465 | Connolly, M<br><br>Tel.+49 89 2399-8021 |

Form PCT/IPEA/416 (July 1992)

# PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

## PCT

### NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark Office, PCT
2011 South Clark Place Room CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

| | |
|---|---|
| **Date of mailing** (day/month/year)<br>10 July 2001 (10.07.01) | |
| **International application No.**<br>PCT/GB00/03892 | **Applicant's or agent's file reference**<br>SPG/P36234WO |
| **International filing date** (day/month/year)<br>11 October 2000 (11.10.00) | **Priority date** (day/month/year)<br>11 October 1999 (11.10.99) |
| **Applicant**<br>BRAITHWAITE, Philip | |

1. The designated Office is hereby notified of its election made:

   [X] in the demand filed with the International Preliminary Examining Authority on:

   09 May 2001 (09.05.01)

   [ ] in a notice effecting later election filed with the International Bureau on:

   _____

2. The election [X] was

   [ ] was not

   made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

| | |
|---|---|
| **The International Bureau of WIPO**<br>**34, chemin des Colombettes**<br>**1211 Geneva 20, Switzerland** | Authorized officer<br>Pascal Piriou |
| Facsimile No.: (41-22) 740.14.35 | Telephone No.: (41-22) 338.83.38 |

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PATENT COOPERATION TREATY

REC'D 07 JAN 2002
WIPO PCT

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference | FOR FURTHER ACTION | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
|---|---|---|
| SPG/P36234WO | | |
| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
| PCT/GB00/03892 | 11/10/2000 | 11/10/1999 |
| International Patent Classification (IPC) or national classification and IPC<br>C09D165/04 | | |
| Applicant<br>~~[INNOVOTA BIOMED LIMITED]~~ ▲ ML LABORATORIES PLC | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

| Date of submission of the demand | Date of completion of this report |
|---|---|
| 09/05/2001 | 03.01.2002 |
| Name and mailing address of the international preliminary examining authority:<br>European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - 0 Tx: 523656 epmu d<br>Fax: +49 89 2399 - 4465 | Authorized officer<br>Marquis, D<br>Telephone No. +49 89 2399 8305 |

Form PCT/IPEA/409 (cover sheet) (January 1994)

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/03892

## I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
**Description, pages:**

| | | | | |
|---|---|---|---|---|
| 1,2,4-6 | as originally filed | | | |
| 3,3a | as received on | 13/12/2001 | with letter of | 13/12/2001 |

**Claims, No.:**

| | | | | |
|---|---|---|---|---|
| 1-21 | as received on | 01/10/2001 | with letter of | 01/10/2001 |

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   - ☐ the description, pages:
   - ☐ the claims, Nos.:
   - ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   *(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application.

   ☒ claims Nos. 19,21.

because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

   ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 19,21 are so unclear that no meaningful opinion could be formed (*specify*):
   **see separate sheet**

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the standard.

   ☐ the computer readable form has not been furnished or does not comply with the standard.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Yes: | Claims | 1-18,20 |
| | No: | Claims | |
| Inventive step (IS) | Yes: | Claims | 1-18,20 |

| | | | |
|---|---|---|---|
| | No: | Claims | |
| Industrial applicability (IA) | Yes: | Claims | 1-18,20 |
| | No: | Claims | |

2. Citations and explanations
**see separate sheet**

**VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:
**see separate sheet**

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
**see separate sheet**

Concerning point III:
Claim 19 relate to a subject-matter considered by the Authority to be covered by the provisions of Rule 67.1(iV) PCT. Consequently, no opinion will be formulated with respect of the industrial applicability of the subject-matter of this claim (Article 34(4)(a)(i) PCT).
Claim 21 has no technical feature, it is therefore not possible to assess on the novelty and inventive merit of this claim.

Concerning point V:
Claims 1-21 of the application have been restricted to an inhaler. Claim 1 has also been restricted to an inhalersealed by a coating on the outer walls of the reservoir.
The amendments received on the 01.10.01 are allowable.
Novelty:
D1 discloses a glass container with a closure stopper (rubber). D1 does not disclose an inhaler.
D2 discloses a coated cartridge within an injection device. The outer walls of the injection device are not coated.
D3 discloses a closure device (stopper) and not an inhaler.
D4 discloses an inhaler which inner walls are coated in order to provide the clogging of the medicament on the inner walls of the inhaler.
D5 discloses a metering device for inhaler. The inhaler may include a moisture absorbent material inside the chamber but not on the outer walls (page 15 §3).
D6 discloses a process of coating to prevent corrosion on metal. D6 does not disclose an inhaler.
D7 and D8 disclose moisture proof sugar coated dosage units. Neither D7 nor D8 discloses an inhaler.

None of the prior art documents discloses an inhaler with a coating on the outer walls. The subject matter of claim 1 is novel over the prior art. The claims 2-18,20 refering to claim 1 are also novel.

Inventive step:
D2 appears to be the closest prior art document because it is the sole document disclosing the use of a parylene coating to improve, among others, the moisture resistance of a medical container. The coating is mainly applied to the inner walls of a

cartridge (containing a medicament) which is itself contained in an injection device. The coating acts as a moisture barrier and prevents a reaction between the medicament and the cartridge when this one is made of metal. As a result of the process used to coat the cartridge (vapor deposition), the coating might be also present on the outer surface of the cartridge (page 13). However, the mechanism of the injection device implies a coating on the inner walls of the cartridge but no benefit of a coating on the outer walls of the cartridge is demonstrated. From D2, the presence of the coating on the outer wall of the cartridge seems to be secondary and can be prevented if it is desired (page 13 line11). Therefore, the use of a coating on the outer walls as a moisture resistant agent is not disclosed in D2. There would be no incentive for the person skilled in the art to use a coating on the outer walls of a capsule for an inhaler. The subject-matter of claims 1-18,20 is inventive.

Concerning point VII:
VII.1 Claim 2 defines an inhaler by the medicament it can contain. This is not a technical feature defining the reservoir means.

Concerning Point VIII:
VIII.1 Claim 21 as no technical feature and should be deleted.

PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| Applicant's or agent's file reference | **FOR FURTHER ACTION** see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below. | |
|---|---|---|
| SPG/P36234WO | | |
| International application No. | International filing date *(day/month/year)* | (Earliest) Priority Date *(day/month/year)* |
| PCT/GB 00/ 03892 | 11/10/2000 | 11/10/1999 |
| Applicant | | |
| INNOVOTA BIOMED LIMITED | | |

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 03 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

[ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

[ ] contained in the international application in written form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readble form.

[ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

[ ] the text is approved as submitted by the applicant.

[X] the text has been established by this Authority to read as follows:

MEDICAMENT DELIVERY DEVICE WITH MOISTURE RESISTANT COATING

5. With regard to the **abstract,**

[X] the text is approved as submitted by the applicant.

[ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. ---

[ ] as suggested by the applicant.

[ ] because the applicant failed to suggest a figure.

[ ] because this figure better characterizes the invention.

[X] None of the figures.

# INTERNATIONAL SEARCH REPORT

International Application No
P[redacted]B 00/03892

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 C09D165/04 B65D83/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 C09D A61M B65D C08G C08L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 9 January 2001 | 17/01/2001 |

| Name and mailing address of the ISA | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL – 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,<br>Fax: (+31-70) 340-3016 | Paalman, R |

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Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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| A | EP 0 045 522 A (MARYLAND CUP CORP) 10 February 1982 (1982-02-10) claim 1 page 6, line 14 - line 17 | 8,26 |
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International Application No
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reservoir means is coated on the outer walls, such that the reservoir means is substantially sealed in the coating and is rendered moisture proof.

According to a further feature of the present invention we provide a medicament delivery device which comprises a medicament reservoir as hereinbefore described.

In an especially preferred embodiment the medicament delivery device is also provided with a moisture resistant coating. Such a coating preferentially covers substantially the whole of the delivery device.

When the medicament reservoir means comprises a bulk reservoir, then the medicament delivery device may preferentially include a metering member. The metering member preferably is also provided with a moisture resistant coating.

According to a yet further feature of the invention we therefore provide a medicament delivery device which comprises a medicament reservoir, a medicament delivery passage and a metering member characterised in that the device is provided with a moisture resistant coating on one or more surfaces. Preferably, the whole of the device is substantially provided with a moisture resistant coating.

The moisture resistant coating may be provided on one or more external or internal surfaces of the body of the medicament delivery device. The moisture resistant coating preferentially coats one or more surfaces of the bulk medicament reservoir. Other surfaces of the body of the medicament delivery device may also be provided with a moisture resistant coating.

The moisture resistant coating may be in the form of any material which is effective to prevent moisture accessing the powder. Typically, it may be applied to those surfaces between which there may be a gap due to relative movement between the surfaces when the inhaler is in use. However, the moisture resistant coating may be applied additionally or alternatively to other surfaces including the whole or part of

## CLAIMS

1. A reservoir means which means is provided with a moisture resistant coating.

2. A reservoir means according to claim 1 characterised in that the reservoir means contains a medicament.

3. A reservoir means according to claim 1 characterised in that the reservoir means is a bulk medicament reservoir.

4. A reservoir means according to claim 1 characterised in that the reservoir means comprises one or more single dose reservoir means.

5. A reservoir means according to claim 1 characterised in that the reservoir means is coated on the outer walls, such that the reservoir means is substantially sealed in the coating and is rendered moisture proof.

6. A reservoir means according to claim 1 characterised in that the reservoir means comprises a spool carrier housing a spool.

7. A reservoir means according to claim 1 characterised in that the moisture resistant coating is a biocompatible coating.

8. A reservoir means according to claim 7 characterised in that the biocompatible coating is a sugar.

9. A reservoir means according to claim 7 characterised in that the moisture resistant coating is a polymer.

10. A reservoir means according to claim 9 characterised in that the polymer is a poly-para-xylylene (parylene).

11. A reservoir means according to claim 1 characterised in that the moisture resistant coating has a thickness of from 0.025 to 75 microns.

12. A medicament delivery device which comprises a medicament reservoir according to claim 1.

13. A medicament delivery device according to claim 7 characterised in that the delivery device is also provided with a moisture resistant coating.

14. A medicament delivery device according to claim 8 characterised in that the moisture resistant coating covers substantially the whole of the delivery device.

15. A medicament delivery device according to claim 6 characterised in that the medicament reservoir means comprises a bulk reservoir.

16. A medicament delivery device according to claim 9 characterised in that the medicament delivery device includes a metering member.

17. A medicament delivery device according to claim 10 characterised in that the metering member is also provided with a moisture resistant coating.

18. A medicament delivery device according to claim 6 characterised in that the medicament reservoir comprises a single dosage reservoir.

19. A medicament delivery device according to claim 12 characterised in that the moisture resistant coating is applied to the outer surface of the reservoir.

20. A medicament delivery device according to claim 18 characterised in that the medicament reservoir comprises a plurality of single dose units hosed in a cartridge.

21. A medicament delivery device according to claim 14 characterised in that the cartridge is also provided with a moisture resistant coating.

22. A medicament delivery device according to claim 6 characterised in that the medicament delivery device is an inhaler.

23. A medicament delivery device according to claim 23 characterised in that the inhaler is a dry powder inhaler (DPI).

24. A medicament delivery device according to claim 23 characterised in that the dry powder inhaler is a TECHNOHALER.

25. A medicament delivery device according to claim 6 characterised in that the moisture resistant coating is a biocompatible coating.

26. A medicament delivery device according to claim 25 characterised in that the biocompatible coating is a sugar.

27. A medicament delivery device according to claim 6 characterised in that the moisture resistant coating is a polymer.

28. A medicament delivery device according to claim 27 characterised in that the polymer is a poly-para-xylylene (parylene).

29. A medicament delivery device according to claim 6 characterised in that the moisture resistant coating has a thickness of from 0.025 to 75 microns.

30. A method of treating a respiratory disorder which comprises the administering of a therapeutically effective amount of a medicament to a patient suffering from such a disorder wherein said medicament is contained in a reservoir.

31. The use of a parylene in the manufacture of a moisture resistant reservoir according to claim 10 and/or a medicament delivery device according to claim 28.

32. A reservoir means or a medicament delivery device substantially as described with reference to the accompanying description.